

REMARKS

In reply to the Office Action dated May 18, 2004, claims 1, 2, 6-7, 47-48 and 50-54 are currently under examination in the Application. By the above amendment, claims 2, 6-7, 47-48, and 50 have been canceled. Claims 1 and 51-53 have been amended for clarity and to remove recitation of canceled subject matter. No new matter has been added. The above amendment is not to be construed as acquiescence to the stated grounds for objection/rejection and is made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Applicants wish to thank the Examiner for acknowledgement of the Information Disclosure Statements submitted June 14, 2001, July 11, 2003, and March 25, 2004. However, Applicants note that a Supplemental Information Disclosure Statement was filed **March 14, 2002** for which we have not received acknowledgement. Applicants respectfully request acknowledgement of the single reference cited in this Information Disclosure Statement.

Priority

The Action objects to the recitation of "related" in the priority claim. Further, the Action contends that the presently claimed SEQ ID NO:335 is not disclosed in any of the parent applications to which priority is claimed and therefore the effective filing date of the instant claims is that of the instant application.

Applicants submit that the priority claim was amended in Applicants' Amendment filed October 14, 2004. By that amendment, Applicants deleted the section beginning at page 1, line 2 and ending at page 1, line 7, thereby disclaiming priority to all prior applications. Accordingly, Applicants submit that the present objections have been obviated.

Claims Rejections – 35 U.S.C. 112, first paragraph (new matter)

Claims 48, 50 and 52-54 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Applicants, at the time the

application was filed, had possession of the claimed invention. In particular, the Action contends that there is no support in the specification for the peptides of claims 48 and 50. Specifically, the Action asserts that the "WT1" recited in claim 48 is interpreted as referring to the peptide of SEQ ID NO:335 rather than the native WT1 sequence as disclosed throughout the specification as filed. Therefore, the Action opines that the residue positions recited in claim 48 are residues of SEQ ID NO:335 and, as such, are not supported by the specification as filed. Likewise, regarding claim 50, the Action alleges that the specification does not disclose what residues of said peptide constitute the HIS tag portion of the fusion protein. The Action goes on to assert that, assuming that the HIS tag encompasses only the 6 HIS residues at positions 3-8 of SEQ ID NO:335, removal of said residues would leave a peptide containing residues 1, 2, and 9-259 of SEQ ID NO:335 and, as such, is not supported by the specification. Concerning claims 52-54, the Action alleges that there is no support in the specification for the ingredients recited in the claims in an "immunogenic composition". Accordingly, the Action concludes that the claims contain new matter.

Applicants respectfully traverse the rejection on the following grounds. As an initial matter, Applicants note that claims 48 and 50 have been canceled without prejudice or acquiescence. Accordingly, the rejection has been obviated as it applies to claims 48 and 50. Nevertheless, in response to the rejection of these claims, Applicants submit that there is simply no basis for interpreting the recitation of "WT1" in claim 48 as the peptide of SEQ ID NO:335. As noted in M.P.E.P. Section 2111, the courts have held that the "PTO applies to verbiage of the proposed claims the *broadest reasonable meaning* of the words in their ordinary usage *as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification.*" (Emphasis added) (See *e.g.*, *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997)). Applicants submit that the Office's interpretation of the claim appears to be completely arbitrary and without any reference to the ample teachings in the specification of the sequence of WT1 and numerous defined peptides thereof, in particular the peptide consisting of amino acid residues 117-139. Given the identification by Applicants of the naturally processed WT1 epitope defined by residues 117-139

of WT1 in the specification as filed (see for example, Table I, SEQ ID NO:2 and Example 5, pages 97-99), and in view of the disclosure as a whole, Applicants submit that the skilled artisan would undoubtedly interpret the claims to mean those residues of the polypeptide of SEQ ID NO:335 that correspond to residues 117-139 of native WT1, and not as residues of SEQ ID NO:335 as outlined by the Office. Further, Applicants submit that the skilled artisan would readily understand which HIS residues to remove and would immediately recognize the resulting truncated portion of WT1 as residues 1-249 of WT1, a fragment of WT1 that is clearly disclosed in the specification as filed (see for example, page 53, lines 20-24 and page 103, line 9-page 104, line 7 and the sequence listing as filed at SEQ ID NO:335). Accordingly, Applicants submit that, when properly interpreted from the perspective of the skilled artisan and in view of the specification as filed, claims 48 and 50 do not contain new matter.

As previously noted, and notwithstanding the foregoing, Applicants have canceled claims 48 and 50 without prejudice or acquiescence and solely to advance prosecution of the application. Applicants urge that the rejection has been obviated and may be properly withdrawn.

With regard to claims 52-54, the Action asserts that "immunogenic composition" with the ingredients recited in the claims is not supported by the specification as filed. Applicants respectfully disagree and submit that the skilled artisan, in view of the specification as filed, and further in view of the level of knowledge within this art, would recognize that the applicants were indeed in clear possession of immunogenic WT1 compositions. Nevertheless, in an effort to expedite prosecution of this application, Applicants have amended the claims, without prejudice, by removing the phrase "immunogenic composition" in favor of the more generic term "composition." Reconsideration of this rejection is thus respectfully requested.

Claims Rejections – 35 U.S.C. 112, first paragraph (written description)

Claims 1, 2, 6-7, 47 and 50-54 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Applicants, at the time the application was filed, had possession of the claimed invention. In particular, the Action

contends that the written description provided in the specification is not commensurate with the scope of the claimed invention in that the claims recite variant peptides allegedly not described in the specification.

Applicants respectfully traverse the rejection. However, solely to advance prosecution of the application, Applicants have amended the claims without prejudice or acquiescence, to remove recitation of the variant language. Applicants reserve the right to prosecute any subject matter modified and/or removed by this amendment in a related application. Applicants submit that the rejection has been obviated and may be properly withdrawn.

Claims Rejections – 35 U.S.C. 102(b)

Claims 1-2, 6-7, 47-48 and 50-51 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by Herlyn *et al.* (WO 95/29995). Further, claims 1-2, 6-7, 47 and 50-54 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by Sugiyama *et al.* (WO 00/06602) as evidenced by EP1103564. In particular, the Action contends that Herlyn *et al.* teach an immunogenic polypeptide containing the amino acids 1-181 of human WT1 and pharmaceutically acceptable excipients. Further, the Action asserts that the peptide of claim 48 is found within the polypeptide taught by Herlyn *et al.* and that the peptide also inherently contains MHC class I binding peptides. Additionally, the Action alleges that the peptide recited in claim 16 of Herlyn *et al.* does not contain a HIS tag. The Action cites Sugiyama *et al.* as allegedly teaching immunogenic MHC class I binding peptides of 9 amino acids in length that are derived from WT1 and wherein the peptides are found in SEQ ID NO:335. Sugiyama also allegedly teaches compositions containing said peptides and a pharmaceutically acceptable carrier or microspheres. The Action contends that microspheres are disclosed in Sugiyama *et al.* as having the properties recited in claim 53 (*e.g.*, preferentially enhancing T cell response).

Applicants respectfully traverse the rejection. However, without acquiescing to the rejection and solely to advance prosecution, Applicants have canceled claims 2, 6-7, 47-48, and 50 without prejudice and have amended claims 1 and 51-53 to recite a polypeptide consisting of the amino acid sequence of SEQ ID NO:335 and to remove recitation of

immunogenic portions. These amendments should not to be construed as acquiescence to the stated grounds for objection/rejection and is made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application. Applicants submit that the rejection has been obviated and may be properly withdrawn.

Provisional Double Patenting

Claims 1-2, 6-7, 47-48 and 50-54 are provisionally rejected under the judicially created doctrine of double patenting over claims 1, 6-7, 46-51, 55, 57 and 59-62 of copending Application No. 09/684,361. Claims 1-2, 6-7, 47 and 50-54 are similarly rejected over claims 104 and 107-112 of copending Application No. 09/164,423. While the claims in each case differ in scope, both sets of claims allegedly encompass similar peptides and compositions. In particular, the Action asserts that the peptide of claim 1 of Application No. 09/684,361 and the peptide of claim 104 of Application No. 09/164,223 are each found in SEQ ID NO:335.

Applicants respectfully request that the rejection be held in abeyance until allowance of the instant application. While in no way admitting that claims 1 and 51-54 are obvious over or anticipated by the claims of Application Nos. 09/684,361 and 09/164,223, at such time as the claims of the instant application are otherwise deemed by the PTO to be in condition for allowance, Applicants will consider filing a terminal disclaimer in the instant application.

Application No. 09/785,019
Reply to Office Action dated May 18, 2004

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all the claims remaining in the application are now believed allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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